



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,344	11/03/2003	Andrew L. Cote SR.	1600/163	5277
2101 7590 01/30/2008 BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 01/30/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/700,344	Applicant(s) COTE ET AL. CT	
	Examiner Elizabeth R. MacNeill	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10-13,16-24,37,38,40-47,49,63-75,77-86 and 88-92 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10-13,16-24,37,40-42,44-47,49,63,65-67,69-75,77-86 and 89-92 is/are rejected.
- 7) ☒ Claim(s) 38,43,64 and 68 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-7, 10-13, 16-24, 74, 75, 77-86, and 88-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Lopez (US 5,700,248).

Lopez teaches a medical valve comprising a housing (10) having an inlet (at 95) and an outlet (at 28, bottom of the housing) having a passageway (Fig 10), a plug member (94, 36a, 98, see Fig 9) movably disposed within the passageway; a substantially flexible, resilient gland member (95) which supports the seal member, which has a seal section (proximal face) aligned with the inlet face (97, see Fig 10) such that the seal section is swabbable. The plug member occludes the passageway and prevents fluid flow through the valve when the valve is in the closed mode (Fig 10). At least some portions of the plug member are rigid (92).

3. Claims 37, 40-42, 44-47, 49, 63, 65-67, and 69-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Collinson et al (US 5,439,451).

Collinson teaches a housing with inlet end (12), outlet end (14), plug (32), gland (30) wherein the gland normally occludes the opening (94) of the plug (via 56).

Allowable Subject Matter

4. Claims 38, 43, 64 and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments have been considered but are not persuasive.

6. Regarding Lopez, Applicant has argued that Lopez does not teach a moveably mounted plug. See Figs 4-5, which show how the plug moves within the valve.

Applicant further argues that the moveable plug does not define a channel for directing fluid through the valve. The seal has a cannula (applicant's narrow definition of a hollow bore with two ends, bore 98 and ends 92 and 96) which directs fluid through the valve (directing fluid into the spike 26 for flow through the valve). As to claim 13, see Fig 9 which shows the gland (95) secured to the plug at 92. It is unclear why the applicant believes that because the plug is distal to the gland it cannot be secured about the gland when the two elements are directly connected in Fig 9-10.

7. Regarding Collinson, applicant had previously argued that the plug was not a cannula that "directs fluid through the valve." This limitation is found in claims 38,43,64, and 68, but not in claims 37 or 63. A cannula is defined as a small, flexible tube (Cambridge). Applicant has not claimed that his cannula has two open ends, as argued. Secondly, there is nothing to suggest that "normally" means "closed." The valve could be a safety valve which is intended to be open and only closes if the connection fails. The rejections are maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

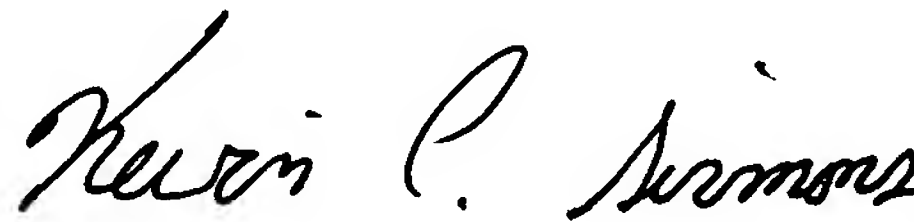
Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

A handwritten signature in black ink, appearing to be 'ERM' followed by a stylized flourish.

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink that reads 'Kevin C. Sirmons'.